Remarks

Applicants thank the Examiner for taking time to discuss the outstanding Office Action with Applicants' undersigned representative on August 28, 2003. In accordance with that discussion, and in view of the present amendment and remarks, reconsideration of the rejections set forth in the Office Action dated April 18, 2003, is respectfully requested, particularly in view of MPEP §2163.07(a).

Rejection of Claims 16-19 Under 35 U.S.C.§ 112, first paragraph

The Examiner rejected claims 16-19 under 35 U.S.C. §112, first paragraph. In paragraph 3 of the office action, the examiner asserted that there "is no support in the specification for a bronchial sub-branch obstruction device for reducing the size of a lung with all the required structural elements or a conduit configured to be passed down a trachea. The current invention is a body *fluid* flow control device for urinary, venous or pulmonic placement (see page 2, lines 13-14 and page 3, lines 5-6)" (Emphasis in original.) The examiner apparently asserts that air (which would be present in a bronchial sub-branch) is not a "fluid" and that the bronchial obstruction device is, therefore, not supported by the specification. However, as discussed with the examiner during the interview of August 28, 2003, applicants submit that air is a fluid. Merriam Webster's Collegiate Dictionary defines a "fluid" as "a substance (as a liquid or gas) tending to flow or conform to the outline of its container." See Exhibit 6 of Declaration of Antony Fields ("the Fields Declaration"), which accompanies this response. Accordingly, air (which is a gas) is indeed a "fluid" according to the dictionary definition of the word.

In paragraph 8 of the office action, the examiner maintained the rejection of claims 16-19 under the first paragraph of 35 U.S.C. §112. The examiner asserted that the "broad disclosure of a flow control device for pulmonic placement does not sufficiently support the claiming of a bronchial sub-branch obstruction device with further structural limitations." Applicants respectfully disagree. As described below, the written description supports all of the structural limitations of claim 16-19, and also supports the functional recitations.

"Obstructing Member Dimensioned for Insertion into a Bronchial Sub-Branch "

The first structural limitation in claim 16 and 18 is "an obstructing member dimensioned for insertion into a bronchial sub-branch " The specification states at page 6, lines 6-8, that the "device is intended to fit with interference with the [body] duct or passageway." Merriam Webster's Collegiate Dictionary defines the word "interference" as "obstruction." See Exhibit 6 of Fields Declaration. Thus, by stating that the device fits with interference with the body passageway, the specification provides written support for use of the term "obstructing member" in claim 16.

The specification further indicates that the resilient seal (which defines the outer diameter of the flow control device) has an outer diameter of approximately 0.349 inches [8.865 mm]. See page 7, lines 5-6 of the '569 application. The specification also indicates that the flow control device has a length of approximately 0.60 inches [15.24 mm]. See page 7, lines 6-7 of the '569 application. According to published empirical data, a sub-branch of a human bronchial passageway can have an average diameter of up to about 9.10 ± 2.05 mm and a length of up to about 19.83 ± 7.78 mm. Nikiforov *et al.*, MORPHOMETRIC VARIABILITY OF THE HUMAN UPPER BRONCHIAL TREE (1982), Table 1, page 292, see Exhibit 2 of Fields Declaration. The specification, therefore, describes a fluid flow control device of a diameter and length that would fit into the diameter and length, respectively, of a human bronchial sub-branch. Accordingly, the specification provides written support for the obstructing member being "dimensioned for insertion into a bronchial sub-branch."

"Outer Dimension Which Is So Dimensioned As To Make Continuous Contact With An Inner Dimension Of The Bronchial Sub-Branch"

The second structural limitation of claims 16 and 18 is that the obstructing member has "an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch." Applicants note the term "dimension" is employed in a qualitative

sense and therefore does not expressly connote a numerical value or unit of measurement. Furthermore, the specification of U.S. Patent No. 6,293,951 to Alferness (from which claims 16-19 were copied) does not provide any numerical dimensions or units of measurement. The captioned application, however, provides both qualitative and numerical written support for this limitation. As discussed above, the specification recites specific dimensions for the flow control device that are within empirically-derived dimensions of human bronchial sub-branches. The specification further describes the dimensions of the flow control device in a qualitative manner. The specification recites at page 4, line 8-9 that the outer seal of the flow control device "has a substantially circular cross section to fit within the body duct or passageway." When the flow control device is placed in a bronchial sub-branch, the similarity of the circular cross-sections of the flow control device and the bronchial sub-branch results in continuous contact between the outer dimension of the flow control device and the inner dimension of the bronchial sub-branch. Thus, the specification supports this structural limitation in a manner that is more descriptive than the '951 patent.

"One-Way Valve"

The last structural limitation in claims 16 and 18 is that the obstructing member "is a one-way valve." The specification explicitly recites that the flow control device includes a one-way valve. For example, the specification states that "the present invention is directed to a body fluid flow control device which includes ... a valve body capable of either or both a pressure threshold for operation and a one-way flow restriction." See page 2, lines 13-16 of the '569 application.

Thus, the specification provides support for all of the structural limitations of claims 16 and 18.

Additional Structural Limitations – Claims 17 and 19

Claims 17 and 19 include the aforementioned structural limitations. Furthermore, claims 17 and 19 include the structural limitation of "a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a

lung portion." The specification describes a fluid flow control device insertion tool, which includes "an outer sheath 88 into which is positioned a fluid flow control device...." See page 11 lines 12-14, Fig. 12 of the '569 application. This section of the specification, in combination with the "pulmonic" nature of the fluid flow control device, provides support for the "conduit" of claims 17 and 19.

Claims 17 and 19 include the additional structural limitation that the obstructing member is "so dimensioned as to be guidable through the conduit and placed in a bronchial sub-branch..." As discussed, the specification indicates that the fluid flow control device can be positioned in the outer sheath 88 and is dimensioned for placement in a bronchial sub-branch. Thus, the specification provides support for all of the structural limitations of claims 17 and 19.

Functional Recitations of Claims 16-19

Claims 16-19 include several functional recitations in addition to the structural limitations described above. The functional recitations of claims 16-19 are that the obstruction member (1) seals the bronchial sub-branch upon placement in the bronchial sub-branch; (2) precludes normal function of the lung portion; and (3) collapses the portion of the lung for reducing the size of the lung; and that the one-way valve permits exhaled air to flow from the lung portion and precludes inhaled air from flowing into the lung portion.

The specification supports such functional recitations. As mentioned, the specification states at page 3, lines 4-6 that the fluid flow control device is for "pulmonic placement", which indicates that the device can be placed in the lung. Merriam Webster's Collegiate Dictionary defines "pulmonic" as "pulmonary", which is defined as "relating to, functioning like, or associated with the lungs." See Exhibit 6 of Fields Declaration. Applicants submit that when the fluid flow control device is placed in the lung, the device seals the bronchial sub-branch upon placement in the bronchial sub-branch, precludes normal function of the lung portion, and collapses the portion of the lung for reducing the size of the lung; and that the one-way valve permits exhaled air from flowing into the lung portion and precludes inhaled air from flowing into

the lung portion. In support, Applicants submits herewith the declaration of Antony Fields at paragraphs.

Rejection of Claims 23-25 Under 35 U.S.C.§ 112, second paragraph

The Examiner rejected claims 23-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that claim 23 is indefinite because it claims two distinct species due to the use of the word "or" between the words "elongate passage" and "outer sheath". Applicants have amended claim 23 to address the Examiner's rejection. Applicants respectfully submit that claim 23, as amended, particularly points out and distinctly claims the subject matter which Applicants regard as their invention. The rejection to claims 24 and 25 is also now overcome by the amendment to claim 23. Applicants, therefore, respectfully request that the rejection of claims 23-25 under 35 U.S.C. § 112, second paragraph now be withdrawn.

Rejection of Claims 20-25 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 20-25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Knapp et al. (USPN 5,984,965) in view of Andersen *et al.* (USPN 5,411,552). The Examiner asserted that Knapp discloses all of the elements of independent claims 20 and 23, but is silent as to the valve being dimensioned for pulmonary placement. The Examiner combined Knapp with Andersen et al., asserting that Andersen et al. describes a valve for placement in the pulmonary artery. According to the Examiner, it would have been obvious to one of ordinary skill in the art to look to the teachings of Andersen et al. to dimension the valve of Knapp et al. for pulmonary placement.

Applicants provide a declaration herewith pursuant to 37 C.F.R. § 1.131 evidencing conception of the claimed invention prior to August 28, 1997 and due diligence from a time prior to August 28, 1997 to the filing of the instant application (all dates masked out of exhibits).

Therefore, it is respectfully submitted that Knapp et al., which was filed on August 28, 1997, is not effective as prior art against the instant application. Accordingly, Applicants respectfully request that the rejection of claims 20-25 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

Prompt and favorable action on the merits of the claims is earnestly solicited. Please contact Applicants' undersigned representative if any issues remain.

Respectfully submitted,

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